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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,892	02/27/2002	Shukti Chakravarti	P-CW 4945	1524

23601 7590 05/18/2004

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EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,892	CHAKRAVARTI, SHUKTI	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1-4, drawn to a method for identifying genes which are up- or down-regulated in intestinal tissue of patients, classified in class 435, subclass 6.

II. Claim(s) 5-7, drawn to a method for determining the phenotype of a cell, classified in various classes/subclasses, for example, class 435, subclasses 6.

III. Claim(s) 8-11, drawn to a kit for assessing a patient's risk of having or developing inflammatory bowel disease, classified in various classes/subclasses, for example, class 435, subclasses 975.

IV. Claim(s) 12, drawn to a **method of doing business** for assessing a patient's risk of having or developing an inflammatory bowel disease, classified in class 707, subclass 104.1

V. Claim(s) 13, drawn to a method for treating a patient, classified in various classes/subclasses, for example, class 530, subclass 300+.

VI. Claim(s) 14-15, drawn to a nucleic acid array, classified in various classes/subclasses, for example, class 536, subclasses 23.1.

VII. Claim(s) 16, drawn to a drug screening assay, classified in class 435, subclass 6.

VIII. Claim(s) 17, drawn to a method for treating an animal having an inflammatory bowel disease, classified in class 530, subclass 300.

IX. Claim(s) 18, drawn to a pharmaceutical preparation for treating an animal having an inflammatory disease, classified in class 424, subclass 278.1.

2. The inventions are distinct, each from the other because of the following reasons:

A. Groups I, II, IV, V, VII and, VIII are all drawn to different methods, and these methods are distinct because they use different method steps, require different reagents and will produce different products and/or results. Thus therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter.

In the instant case, each of the methods requires different steps and produces a different result. That is, the method of Group I method identifies genes; the method of Group II is drawn to determining the phenotype of a cell; Group IV method is drawn to method of doing business; the method of Group V is drawn to treating a patient; the method of Group VII is drawn to a drug screening assay; and group VIII is drawn to a method of treating an animal. Each one of these methods result in a distinctly different end result that requires different steps to achieve and thus represent patentably different methods.

B. Groups VI (nucleic acid array) and group IX (a pharmaceutical preparation) represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter.

In the instant case, the nucleic acid array of group VI is different from group VIII, since the group drug compounds are structurally and functionally distinct from the nucleic acid array group VI. The nucleic acid array of Group VI is completely different in structure than any of the products containing chemical compounds of group VIII.

C. The product of group VIII, and group VII are related as the product and process of making the product. The inventions of group VIII and VII are distinct for the following reasons: (i) the process of making or obtaining as claimed in group VII can be used to obtain a different product and the pharmaceutical composition of group IX can be prepared using different methods of screening, such as immunological screening. Thus the restriction between the groups is proper.

D. Groups VIII (process of use) and group IX (product) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process, such as diagnostic assay.

3. Note that the kit of Group III is not claimed as being used in any of the methods of Groups and thus is not related to any of these methods. The kit of group III however, can be used in any of the several different group methods, thus restriction of group III is proper.

4. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Each of the different methods and products would require completely different searches in the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

5. Claims 1-18 are generic to a plurality of disclosed patentably distinct species comprising

A) If group I is elected applicants are requested to elect the following:

a) Applicants are requested to elect a group of genes expressed by intestinal tissue of animal without apparent symptoms;

b) Applicants are requested to elect a group of genes expressed by intestinal tissue of animal with apparent symptoms;

B) if group II is elected applicants are requested to elect a single gene from table I, which has differential expression;

C) if group III is elected applicants are requested to elect the following:

a) five genes from table 1;

b) nucleic acid probes;

D) if group V is elected applicants are requested to elect the following:

a) a single gene, which has a differential expression;

b) course of treatment (i.e., which prescription drugs);

E) if group VI is elected applicants are requested to elect the following:

a) five different IBD gene probes present in the array and the sequences of the probes;

b) a single species of solid support;

F) if group VII is elected applicants are requested to elect the following:

a) a single species of test compound;

b) a single IBD gene (which has a differential expression in presence of the test compound);

G) if either group VIII or group are elected applicants are requested to elect the following:

a) a single compound used in the method.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

7. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
16 May 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER